



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,932	02/08/2002	Robert J. Nordstrom	MDS-022CI	1037
51414 7590 01/11/2007 GOODWIN PROCTER LLP PATENT ADMINISTRATOR EXCHANGE PLACE BOSTON, MA 02109-2881			EXAMINER ROY, BAISAKHI	
			ART UNIT	PAPER NUMBER
			3737	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/11/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/071,932	Applicant(s) NORDSTROM ET AL.	
	Examiner Baisakhi Roy	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24,26-34,36-38,40-44,46,47 and 49-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24,26-34,36-38,40-44,46,47 and 49-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of: _____
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10/5/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments filed 10/5/06 have been fully considered but they are not persuasive. With respect to Wu et al., the reference clearly teaches processing fluorescence spectral data and adjusting the spectrum with reflectance spectrum (col. 2 lines 18-19) allowing correlation of clinically obtained in vivo tissue spectra with fluorophores present within the tissue. Therefore even though Wu et al. do not explicitly state determining whether the specimen has a known condition with fluorescence and then obtaining reflectance data, Wu et al. clearly includes the steps of obtaining fluorescence and then reflectance data and this would necessarily suggest that one is used to screen and the other for further analysis, especially since spectral data is obtained in that order. Utzinger et al. is directed to obtaining reflectance and fluorescence data of cervical tissue. Therefore the combination of Wu et al. and Utzinger et al. is clearly directed to obtaining spectral data of tissue, which includes both fluorescence and reflectance data for more complete and uniform characterization of the tissue. Therefore the previous rejection still stands.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3737

2. Claims 24, 26-31, 36-38, 40, 41, 46, 47, and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (5452723) in view of Utzinger et al. Wu et al. disclose a system and method of classifying a biological specimen by screening a test specimen for a known health condition such as cancer (col. 3 lines 24-28) by obtaining fluorescence spectral data from specimens and then processing reflectance data from the test specimen (abstract, col. 2 lines 12-19, col. 3 lines 1-12). Wu et al. teach obtaining fluorescence data and if it is not determinate, adjust the spectrum with the reflectance spectrum. The test specimen is illuminated with monochromatic radiation (col. 4 lines 55-67, col. 5 lines 39-67, col. 6 lines 1-3). The system also includes obtaining additional optical information (col. 1 lines 42-45). Wu et al. do not explicitly teach using the system to evaluate cervical tissue. In the same field of endeavor Utzinger et al. disclose a method and system of determining a condition of a cervical tissue by obtaining optical information by using a data collection module to obtain reflectance spectral data from a cervical tissue and a computation module to determine whether fluorescence spectral data from said cervical tissue is definitive of said cervical tissue having a known condition, obtaining and processing reflectance spectral data of said tissue using reference reflectance spectral data from a plurality of reference specimens having said condition, and determining said condition of said cervical tissue based on processing and optical information (abstract, col. 2 lines 24-39, col. 3 lines 48-59, col. 4 lines 7-32 lines 57-63, col. 23 lines 4-8, col. 25 lines 56-67, col. 26 lines 20-67, col. 31 lines 49-67, col. 32 lines 1-20).

Utzinger et al. teach said method and system to include determining a condition or a known state of health comprising one of the conditions of normal squamous tissue, metaplasia, CIN I, and CIN II/III (col. 25 lines 53-67, col. 26 lines 20-38, col. 35 lines 4-24, col. 36 lines 1-43).

Utzinger et al. teach said reference reflectance spectral data to comprise of an average amplitude for each of plurality of wavelengths, determining a residual amplitude at each of plurality of wavelengths by subtracting an average amplitude of said reference reflectance spectral data from an amplitude of said reflectance spectral data of said cervical tissue, and where determining said condition of said cervical tissue comprises comparing the residual amplitude at each of said wavelengths to one or more sets of reference residual reflectance spectral data (col. 18 lines 41-62, col. 21 lines 1-12 lines 46-67, col. 22 lines 1-16, col. 23 lines 4-18, col. 26 lines 20-50, col. 29 lines 21-47, col. 30 lines 58-67, col. 31 lines 49-67, col. 32 lines 1-20 lines 56-67, col. 33 lines 1-40, col. 35 lines 4-24, col. 39 lines 20-48, fig. 20-48).

It would have therefore been obvious to one of ordinary skill in the art to use the teaching by Utzinger et al. to modify the teaching by Wu et al. for the purpose of effectively screening cervical tissue for a known state of health (col. 44 line 17-33).

3. Claims 32-34 and 42-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. in view of Utzinger et al. and further in view of Gombrich et al. Wu et al. do not explicitly teach the use of video information and optical image as the addition optical information source. Gombrich et al. disclose a method and apparatus for determining a condition of cervical tissue by obtaining optical information

Art Unit: 3737

with the use of video information and optical image (col. 3 lines 59-67, col. 4-5). It would have therefore been obvious to one of ordinary skill in the art to use the image display teaching by Gombrich et al. to modify the teaching by Wu et al. for the purpose of effectively visualizing the optical information from the test specimen.

Conclusion

2. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Baisakhi Roy whose telephone number is 571-272-7139. The examiner can normally be reached on M-F (7:30 a.m. - 4p.m.).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on 571-272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3737

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

b²

BR


BRIAN L. CASLER
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700